A216.E2048
JACC March 9, 2010
Volume 55, issue 10A

i2 SUMMIT

THE FIRST US STUDY TO ASSESS THE FEASIBILITY AND SAFETY OF ENDOCARDIAL DELIVERY OF ALLOGENIC MESENCHYMAL PRECURSOR CELLS IN PATIENT WITH HEART FAILURE: THREE-MONTH INTERIM ANALYSIS

i2 Poster Contributions
Georgia World Congress Center, Hall B5
Monday, March 16, 2009, 9:30 a.m.-10:30 a.m.

Session Title: Endovascular and New Technologies
Abstract Category: PCI - Cell Therapy & Angiogenesis
Presentation Number: 2505-507

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Background: Previous preclinical studies of allogenic mesenchymal precursor cell (AMPCs) transplantation as potential therapy for heart failure have demonstrated feasibility, safety, and proof of concept that AMPCs enhance angiogenesis, stimulate endogenous myogenesis and improve myocardial performance. This study is designed to evaluate the safety and efficacy of AMPC transplantation to patients (pts) with ischemic (ICM) and nonischemic cardiomyopathy (NICM).

Methods: A Phase II, dose escalating, randomized, single blind, multicenter clinical trial was designed to enroll 60 pts divided into 3 groups of 20. Pts with ICM and NICM, NYHA II-IV, ejection fraction (EF) <40% were randomized in a 3:1 fashion with 15 pts in each cohort to receive 25, 75 or 150 million AMPCs by endoventricular injection, group A, B or C respectively. Five subjects received standard-of-care treatment with mock mapping/injection procedures. We are reporting on the first cohort. AMPCs were obtained from a single donor and transplanted along the border zone of a myocardial infarction in ICM pts via the Myostar TM injection catheter. Pts were followed for 3 months to evaluate feasibility, safety, and efficacy in regard to mortality, procedural complications, acute and subacute immune response, quality of life (QOL) and echocardiographic variables.

Results: To date, 20 subjects were enrolled. AMPC transplant procedures were successful with no procedure related complications. No arrhythmias related to AMPC transplantation were observed. At three month follow up; Human Leukocyte Antibody increased in one patient with no clinical consequence. Blinded core laboratory echocardiography evaluations showed an overall improvement in EF of (29.7 + 2.5 to 36.7 + 2.3, p= 0.029) 33% in the treated group and a decrease by (33.4 + 3.4 to 31.9 + 5.4, P = 0.6) 6% in the control group. In the most severe patients with EFs < 30%, the EF increased by (23.5 + 1.1 to 34.1 + 3.2, p = 0.02) 50% (n =9) while the control group decreased by (27 + 2.0 to 21.5 + 2.7, p = 0.5) 19% (n = 2). QOL values will be presented.

Conclusions: AMPCs transplantation via endoventricular delivery to pts with heart failure was well tolerated, feasible, safe and significantly improved EF.